AWARD NUMBER: W81XWH-15-1-0374

TITLE: Strength at Home Couples Program to Prevent Military Partner Violence

PRINCIPAL INVESTIGATOR: Casey T. Taft, Ph.D.

CONTRACTING ORGANIZATION:

Boston VA Research Institute, Inc.
Boston, MA 02130

REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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6. AUTHOR(S)
Casey T. Taft, Ph.D.
Casey.Taft@va.gov

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Boston VA Research Institute, Inc.
Boston, MA 02130

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The *Strength at Home Couples* (*SAH-C*) program was developed to prevent intimate partner aggression (IPA) in at risk couples among service members and their partners. Results from multiple studies attest to the efficacy of the intervention in VA and community contexts. Before widespread adoption of *SAH-C* on military installations occurs, it is important to examine its effectiveness in the military context and to identify any potential barriers to implementation. A Hybrid Type-I Implementation-effectiveness research design will allow the research team, comprising investigators with expertise in treatment development, efficacy and effectiveness research, and implementation science, to investigate the effectiveness of *SAH-C* in a military sample while identifying potential implementation barriers. The proposed study site is Madigan Army Medical Center. The proposal is relevant to the topic area calling for submissions to provide "Service Members and/or Families with skills to handle situations that may invoke grief, guilt or anger and prevent the development of a negative trajectory." The stated goal of *SAH-C* is to prevent negative relationship trajectories from occurring in military families and to develop skills to build resilience with respect to the impacts of trauma on relationships.

15. SUBJECT TERMS-

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Annual Report for Period: Oct 30, 2015 to Sept 30, 2016

Strength at Home Couples Program to Prevent Military Partner Violence Dr. Casey Taft, PI

1. **INTRODUCTION:** Intimate partner aggression (IPA) is a national public health problem. The *Strength at Home Couples* (*SAH-C*) program was developed to prevent IPA in at risk couples before it begins among military personnel and their partners. Results from multiple studies attest to the effectiveness of the intervention in VA settings and community contexts. Before widespread adoption of *SAH-C* on military installations can occur, it is important to examine its effectiveness in the military context and to identify any potential barriers to implementation. The goal of the proposed study is to test the effectiveness of *SAH-C* for military couples on an installation and to examine potential barriers and facilitators for the successful implementation of the program within this setting. A Hybrid Type-I Implementation-effectiveness research design will allow the research team, comprising investigators with expertise in treatment development, efficacy and effectiveness research, and implementation science, to simultaneously investigate the effectiveness of *SAH-C* in a military sample while identifying potential implementation barriers. Considering the scope of the IPA problem, and since there is currently no IPA prevention intervention used on military installations, the proposed research is timely and much needed. This study has the potential not only to alleviate and prevent the suffering of military families, but also to advance the clinical science in this field of study and better understand how we might prevent violence among our service members and their partners.
2. **KEYWORDS:** iIntimate partner violence, domestic violence, partner violence, prevention, veterans, military, couples treatment, marital relationship, trauma, PTSD, relationships, implementation
3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**
- Prepare Regulatory Documents and Research Protocol for Phase I (months 1-3; 67% complete)
    - Major activities include preparing IRB submissions for all sites. IRB approval has been obtained from Boston (Dec 2015) and Palo Alto (July 2015), and is pending at Northern Illinois and Fort Carson.
- Hire and Train Study Staff (months 1-6; 50% completed by month 3)
    - The major activities have been to hire and train a research technician at the Boston home site (accomplished Dec 2016) and to train study staff at the site of the implementation, which originally was Madigan Army Medical Center (MAMC). Due to staffing problems, we are in the process of moving the active site to Fort

Carson (instead of MAMC). A request for this change will be submitted under a separate cover to Jennifer Hayden.

- Recruitment and Intervention for Phase I (months 1-10; 50% complete)
    - The major activities have been to revise the manual (accomplished Sept 2016), revise data collection plan through discussions with Dr. Milner at Northern Illinois University, and revise the implementation assessment through discussions with Dr. Wiltsey-Stirman at VA Palo Alto (accomplished July 2016). As mentioned above, recruitment has been delayed due to needing to change implementation sites.

Clinical Trial Status

Recruitment has not begun

No amendments this period

No adverse events

- **What opportunities for training and professional development has the project provided?**
    - Nothing to Report
- **How were the results disseminated to communities of interest?**
    - Nothing to Report
- **What do you plan to do during the next reporting period to accomplish the goals?**
    - HRPO approval is pending
    - We will request IRB approvals for Fort Carson and Northern Illinois University
    - We will request a change of implementation site from Madigan Army Medical Center to Fort Carson Army Community Services. Once IRB approval is obtained, we will be training staff there and begin recruitment for Phase I.

4. **IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

- **What was the impact on the development of the principal discipline(s) of the project?**
    - *Nothing to Report*
- **What was the impact on other disciplines?**
    - *Nothing to Report*
- **What was the impact on technology transfer?**
    - *Nothing to Report*

- **What was the impact on society beyond science and technology?**
  - *Nothing to Report*

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**
- Two changes are pending approval from the Contract Specialist Jennifer Hayden:
- We are requesting the change of the implementation site for reasons described in the next section.
- We have identified an increased need for technical help at the Boston site and eliminated 2 consultant roles that were deemed less crucial to the study; therefore, the money saved from the consultant fees is being reallocated to research assistant salary in years 3 and 4.
- **Actual or anticipated problems or delays and actions or plans to resolve them**

  As we began planning the implantation at MAMC, it became clear that staff there did not have the promised time to participate in the study. With the help of Co-I Robichaux, we approached several departments to identify a site PI and begin IRB submissions. As of August 2016, no site PI had been identified, and Co-I Robichaux recommended moving the program to Fort Carson. We are in the process of requesting approval to move the site for recruitment and intervention from Madigan Army Medical Center (Diane Debiec, site PI) at Joint Base Lewis McChord to Army Community Services (ACS) at Fort Carson. The new site PI will be Jill Nugin. Ms Nugin has already identified 4 staff people who have expressed interest in delivering the intervention and assisting with training and research components of the project.

- **Changes that had a significant impact on expenditures**
  - We are requesting to eliminate the consultant roles for Dr. Monson and Dr. King, and requesting those funds be reallocated to research technician salary in Years 3 and 4
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
  - N/A
- **Significant changes in use or care of human subjects: N/A**
- **Significant changes in use or care of vertebrate animals: N/A**
- **Significant changes in use of biohazards and/or select agents: N/A**

6. **PRODUCTS:**

Nothing to Report

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name:	Dr. Casey Taft
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-9323-3190
Nearest person month worked:	1.8
Contribution to Project:	Dr. Taft is in charge of training and supervising project staff via weekly telephone meetings with on-site study personnel and separate weekly meetings with those involved with data management and analysis, and will participate in all aspects of the implementation of the treatment program.
Funding Support:	Boston VA Research Institute

Name:	Dr. Shannon Wiltsey-Stirman
Project Role:	Consortium-PI
Researcher Identifier (e.g. ORCID ID):	0000-0001-9917-5078
Nearest person month worked:	1
Contribution to Project:	Dr. Wiltsey-Stirman will contribute to the implementation-related data collection and analyses. She will oversee and assist with the implementation-related data collection, analysis, and interpretation. Furthermore, they have completed all IRB related duties for their site at Palo Alto.
Funding Support:	Alto Veterans Institute for Research (PAVIR)

Name:	Dr. Robin Weatherill
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	N/A

Nearest person month worked:	6
Contribution to Project:	Dr. Weatherill oversees administration of the project from the VA Boston Healthcare System, including coordination with the project sites doing the implementation, preparation of IRB submissions, management of data received from the sites, and supervision of research technicians.
Funding Support:	Boston VA Research Institute

Name:	Dr. Suzannah Creech
Project Role:	Consortium-PI
Researcher Identifier (e.g. ORCID ID):	0000-0002-6582-1673
Nearest person month worked:	1
Contribution to Project:	Dr. Creech is in charge of co-managing training of staff at the study site. She also participates in weekly/biweekly meetings to provide consultation on project progress and help address any problems that may arise.
Funding Support:	Central Texas Veterans Research Foundation

Name:	Tracie Ebalu
Project Role:	Research Technician
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	10
Contribution to Project:	Provides administrative and data management support for all aspects of the project at the VA Boston Healthcare System.
Funding Support:	Boston VA Research Institute

Name:	Christopher Chiu
Project Role:	Research Technician
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Provides administrative and data management support for all aspects of the project at the VA Boston Healthcare System. Christopher Chiu, a new research technician, has been added to the project starting 08/08/16 and will responsible for administrative and data management support for all aspects of the project at the VA Boston Healthcare System. He will also be in charge of coordination among project sites once Dr. Robin Weatherill leaves on 09/30/16. All staff members were credentialed and amendments were submitted to, and approved by, the R&D committee at the Boston VA Medical Center to include them as study staff.
Funding Support:	Boston VA Research Institute

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

We are in the process of requesting the change of site to Fort Carson, and therefore a new Site PI, Jill Nugin. Initially, we were planning to conduct research at Madigan with Diane Debiac as site PI, who left her position abruptly. We made numerous attempts to connect with Ms. Debiac's replacements to designate site personnel, but were unsuccessful due to time constraints and unresponsiveness. As a result, we found that it was in the project's best interest to change the study site to Fort Carson, and designate a new site PI, Jill Nugin, to avoid further progress hindrance.

- **What other organizations were involved as partners**

a.) Organization name: Palo Alto Veterans Institute for Research (PAVIR)**Location:** Palo Alto Veterans Institute for Research
3801 Miranda Ave
P. O. Box V-38
Palo Alto, CA 94304-0038

Partner's Contibution to the Project: Subaward, collaboration, Other- help with implementation of program (see above table for more information)

b.) Organization name: Dr. Suzannah Creech from VISN 17 Center of Excellence for Research on Returning War Veterans

Location: Central Texas Veterans Research Foundation
1901 South 1st Street
Temple, TX 76504

Partner's Contibution to the Project: Subaward, collaboration, Other- clinical trainer and consultor (see above table for more information)

8. **SPECIAL REPORTING REQUIREMENTS**

- **QUAD CHARTS:** *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. ***DO NOT RENUMBER PAGES IN THE APPENDICES.***

Strength at Home Couples Program to Prevent Military Partner Violence

PT140092, Psychological Health/Traumatic Brain Injury Research Program
W81XWH-14-PHTBI-PHRA

PI: Casey Taft, Ph.D. **Org: Boston VA Research Institute, Inc.**

Study/Product Aim(s)

- To test the effectiveness of *SAH-C* for military couples on an installation.
- To explore differences in compliance and process factors across conditions
- To facilitate future implementation of *SAH-C*

Approach

A Hybrid Type-I Implementation-effectiveness research design will allow the research team, comprising investigators with expertise in treatment development, efficacy and effectiveness research, and implementation science, to simultaneously investigate the effectiveness of *SAH-C* in a military population while identifying any barriers to implementation that would need to be addressed before *SAH-C* could be successfully implemented on a larger scale.

Timeline and Cost

Activities / CY	15	16	17	18
Pre-Conditions, hire staff, obtain IRB approval				
Begin Phase 1 Pilot Study				
Begin Phase II Enrollment and Treatment Implementation				
Complete Follow-up Assessments, Analyze Data				
Estimated Budget ($711k)	**$57k**	**$219k**	**$223k**	**$212k**

Updated: (9/30/16)

Goals/Milestones

CY15 Goal – Pre-Conditions

☐Refine and review treatment manual; staff hired and trained

CY16 Goals – Preconditions and Pilot Study

☐IRB approval obtained from VA, pending from other sites and DoD

CY17 Goal – Randomized controlled trial

❑ Pilot study intervention cases will be conducted. Data from pilot study will be used to inform refinements to manual and integrity measures

☐Recruitment, assessment, interventions, and follow-up for Phase II

CY18 Goal – Randomized controlled trial

☐ Continue recruitment, assessment, interventions, and follow-up for Phase II

☐ Data analysis and preparation for conference presentations will occur

Budget Expenditure to Date

Projected Expenditure: $166.5K

Actual Expenditure: $52,049

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6. AUTHOR(S) Casey Taft, Ph.D., Shannon Wiltsey-Stirman, Ph.D., Robin Weatherill, Ph.D., Christopher Chiu, BA

E-Mail: Christopher.Chiu2@va.gov

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5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Boston VA Research Institute, Inc.
150 South Huntington Avenue
Research 151-B
Boston, MA 02130

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

There are no significant research findings to report during this period since no data has been gathered.

15. SUBJECT TERMS
Trauma, Treatment, Intimate Partner Violence, Veteran Health

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STATEMENT OF WORK – Revised Sept 28. 2016
PROJECT START DATE Sept 01, 2015
CHANGES REQUESTED FOR Oct 1, 2016

Site 1: Boston VA Research Institute, Inc. /VA Boston Healthcare System
150 S. Huntington Ave.
Boston, MA 02130
PI: Casey T. Taft, Ph.D. (CT)
Coordinator: TBN
Data Core Manager: TBN

Site 2: Fort Carson Army Community Services
6001 Wetzel Ave
Fort Carson, CO 80913
Site-PI: Jill Nugin, M.Ed. (JN)
Coordinator: Rene Robichaux, PhD (RR)

Abbreviations: VA BHS= VA Boston Healthcare System; FC ACS = Fort Carson Army Community Services

Specific Aims: (1) To test the effectiveness of *SAH-C* for military couples on an installation, we will conduct a randomized trial comparing 10 sessions of *SAH-C* to 10 sessions of Supportive Therapy (*ST*) under clinically representative conditions, with 150 couples who are at risk for the development of IPA; (2) To explore differences in compliance and process factors across conditions, we will compare session attendance, homework compliance, therapeutic alliance, and group cohesion; (3) To facilitate future implementation of *SAH-C*, we will employ a mixed-methods approach, guided by complementary implementation frameworks, to examine potential barriers, facilitators, and potential for intervention refinement.

	Year 1				**Year 2**				**Year 3**				**Year 4**			
Target Enrollment (per quarter)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
VA BHS	-	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FC ACS	-	-	0	0	0	0	10	20	20	20	20	20	20	20	0	0
Target Enrollment Cumulative	-	-	**0**	**0**	**0**	**0**	**10**	**20**	**20**	**20**	**20**	**20**	**20**	**20**	**0**	**0**

Specific Aim 1: (1) To test the effectiveness of *SAH-C* for military couples on an installation, we will conduct a randomized trial comparing 10 sessions of *SAH-C* to 10 sessions of Supportive Therapy (*ST*) under clinically representative conditions, with 150 couples who are at risk for the development of IPA.

Research Sites

	Timeline	**VA BHS**	**FC ACS**
Major Task 1: Refine and finalize SAH-M and Duluth Model Interventions.	Months		
Subtask 1: Prepare Regulatory Documents and Research Protocol for Phase I			
If Applicable, coordinate with Sites for CRADA submission	1-3	CT	JN
If Applicable, coordinate with Sites for material transfer agreements (MTAs) or clinical trial agreements (CTAs) submission	1-3	CT	JN
If Applicable, coordinate with Sites for nondisclosure agreements (NDAs).	1-3	CT	JN
Refine eligibility criteria, exclusion criteria, screening protocol	1-3	CT	JN
Finalize consent form & human subjects protocol	1-3	CT	JN
Coordinate with Sites for IRB protocol submission	1-3	CT	JN
Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	1-6	CT	JN
Submit amendments, adverse events and protocol deviations as needed	As Needed	CT	JN
Coordinate with Sites for annual IRB report for continuing review	Annually	CT	JN
Milestone Achieved: Local IRB approval at VA BHS	3	CT	JN
Milestone Achieved: HRPO approval for all protocols and local IRB approval through VA BHS.	6	CT	JN
Major Task 2: Coordinate Study Staff for Clinical Trials.	Months		
Subtask1: Hiring and Training of Study Staff			
Coordinate with Sites for job descriptions design	1-4	CT	JN
Advertise and interview for project related staff	1-6	CT	JN
Coordinate for space allocation for new staff	1-6	CT	JN
Coordinate with Sites for Independent Evaluators hiring and trainings	1-6	CT	JN
Coordinate with Sites for training Independent Evaluators until 100% concordance	1-6	CT	JN
Milestone Achieved: Research staff trained	1-6	CT	JN

Subtask 2: Facilitate and Coordinate with Sites for hiring, training, supervision and fidelity checks as needed for attrition			
Coordinate with Sites for training Independent Evaluators to maintain 100% concordance	8-20	CT	JN
Milestone Achieved: Maintained trained and available Independent Evaluators throughout duration of both clinical trials	8-20	CT	JN
Major Task 3: Phase I Recruitment and Intervention			
Subtask 1: Review and refine manual	1-10		
Subtask 2: Recruit pilot intervention cases	18-21	CT	JN
Subtask 3: Conduct pilot intervention	18-21	CT	JN
Subtask 4: Baseline and follow-up assessments	18-21	CT	JN
Subtask 5: Refine treatment integrity measures	18-21	CT	JN
Subtask 6: Obtain IRB approval for Phase II	18-21	CT	JN
Milestone Achieved: Phase I complete	21		
Milestone Achieved: IRB approval for Phase II obtained, protocol for Phase II developed	21		
Specific Aim 2 & 3: (2) To explore differences in compliance and process factors across conditions. (3) To facilitate future implementation of *SAH-C*, we will employ a mixed-methods approach, guided by complementary implementation frameworks, to examine potential barriers, facilitators, and potential for intervention refinement.			
Major Task 1: Phase II Recruitment and Intervention			
Subtask 1: Recruit participants	21-39	CT	JN
Subtask 2: Baseline assessments	21-39	CT	JN
Subtask 3: Deliver Interventions	24-42	CT	JN
Subtask 4: Follow-up assessments	26-44	CT	JN
Milestone Achieved: Phase II complete	44		
Major Task 2: Post-Intervention			
Subtask 1: Analyze and Write Up Results	42-48	CT	JN
Milestone Achieved: Study completion	48	CT	JN